

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

TURLOCK IRRIGATION DISTRICT, on
behalf of itself and all others similar situated,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION, PAR
PHARMACEUTICAL, INC., and ENDO
PHARMACEUTICALS, INC.

Defendants.

Civil Action No. 1:18-cv-6776

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

TABLE OF CONTENTS

	Page
I. NATURE OF THE ACTION	1
II. INTRODUCTION	2
III. JURISDICTION AND VENUE	5
IV. THE PARTIES.....	6
V. REGULATORY FRAMEWORK	8
A. The Regulatory Structure for Approval and Substitution of Generic Drugs.	8
1. The Hatch-Waxman Amendments.....	9
2. ANDA paragraph IV certifications.....	10
3. The first filer’s 180-day exclusivity period.	11
B. The Competitive Effects of AB-Rated Generic Competition.....	12
1. The first AB-rated generic is priced below the brand.....	13
2. Later generics drive prices down further.	14
3. Brand manufacturers are incentivized to sell an AG when facing generic entry.	15
C. Pharmaceutical Manufacturers Game the Regulatory Structure to Impair Competition.....	17
1. No-AG agreements enable manufacturers to share the gains from conspiring.....	20
VI. EXFORGE CONSPIRACY	23
A. 1992-2002: Novartis Applies for and Obtains Amlodipine and Valsartan Patents.	23
B. In 2007, Novartis Combines Amlodipine and Valsartan to Create a New Blood Pressure-Lowering Drug.....	24
C. Fall 2007: Par and Synthon File ANDAs for Generic Versions of Exforge.....	25
D. 2010: The FDA Grants Tentative Approval of Par’s ANDA for the Generic Version of Exforge.....	26

E.	Novartis Does Not File Suit against Par or Synthron, and, Even If It Had, Novartis Would Have Been Unsuccessful.....	26
1.	The '728 Patent was no barrier to generic competition.	28
2.	Par's ANDA does not infringe on the '197 Patent.	31
F.	2011: Novartis Enters into an Agreement with Par.	33
1.	The Anticompetitive Agreement was a payment to Par from Novartis.....	34
2.	The value of the Anticompetitive Agreement to Novartis and Par.....	35
G.	2013: The FDA Grants Final Approval.	38
H.	2014: Par Launches a Generic Version of Exforge; Novartis Does Not.	38
I.	March 2015: 180 Days After Par's Generic Exforge Launches, More Generics Launch.....	40
VII.	ANTICOMPETITIVE EFFECTS AND EFFECTS ON INTERSTATE AND INTRASTATE COMMERCE.....	41
VIII.	MONOPOLY POWER AND MARKET DEFINITION.....	44
IX.	CLASS ACTION ALLEGATIONS.....	45
X.	DEFENDANTS' FRAUDULENT CONCEALMENT TOLLED THE APPLICABLE STATUTES OF LIMITATIONS AND DELAYED ACCRUAL OF PLAINTIFF'S CAUSES OF ACTION.....	49
XI.	CONTINUING VIOLATIONS.....	51
XII.	CLAIMS FOR RELIEF.....	51
XIII.	DEMAND FOR JUDGMENT.....	84
XIV.	JURY DEMAND.....	85

Plaintiff Turlock Irrigation District (“Plaintiff”), on behalf of itself and all others similarly situated, files this Complaint against Defendants Novartis Pharmaceuticals Corporation, Par Pharmaceutical, Inc., and Endo Pharmaceuticals, Inc. (collectively, “Defendants”). Plaintiff’s claims stem from Defendants’ anticompetitive scheme to unreasonably restrain competition in the market for Exforge® and its AB-rated generic equivalents sold in the United States. Plaintiff’s allegations are made on personal knowledge as to Plaintiff and Plaintiff’s own acts and upon information and belief as to all other matters.

I. NATURE OF THE ACTION

1. As detailed below, Defendants entered into a pay-for-delay agreement (the “Anticompetitive Agreement”) whereby (1) Par agreed not to compete in the market for Exforge from at least September 21, 2012 until September 30, 2014, thereby allocating the entire Exforge market to Novartis until that date; and (2) Novartis agreed not to compete in the generic Exforge market from September 30, 2014 to March 30, 2015 thereby allocating the entire market for generic versions of Exforge to Par for that six-month period. The purpose and effect of the agreement between Defendants was: (a) to delay generic entry of Exforge in order to lengthen the period in which Novartis’s brand Exforge could monopolize the market and make supra-competitive profits; (b) to keep an authorized generic off the market during Par’s 180-day generic exclusivity period, thereby allowing Par to monopolize the generic market for Exforge during that period and make supra-competitive profits; (c) to prevent any potential patent litigation relating to Exforge and its generic equivalents; and (d) to raise and maintain the prices that Plaintiff and other members of the Class would pay for Exforge at supra-competitive levels until the effects of Defendants’ anticompetitive conduct ceased. Defendants’ scheme allowed them to make hundreds of millions of dollars from the supra-competitive pricing of Exforge.

2. Absent this unlawful and anticompetitive agreement, Plaintiff and members of the class it seeks to represent in this complaint would have benefited from competition for generic versions of Exforge earlier than it did, and would have been able to purchase Exforge at significantly lower prices, rather than being forced to pay supra-competitive prices for branded Exforge. Plaintiff seeks to represent a class of all end-payor purchasers of Exforge or its generic equivalent from September 21, 2012 until the effects of Defendants' conduct ceased. Plaintiff's allegations are based on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

II. INTRODUCTION

3. **Novartis develops Exforge.** In 2007, Novartis created Exforge, the first high blood pressure medication to combine the calcium channel blocker ("CCB") amlodipine besylate with the angiotensin-II receptor blocker ("ARB") valsartan. Novartis claimed that Exforge offered patients the convenience of a reduced pill load for their hypertension medication that would increase patient adherence. On June 20, 2007, the FDA approved Novartis's New Drug Application ("NDA") for Exforge tablets.

4. **Par and Synthon were the first generic filers.** In 2007, Par and Synthon Pharmaceuticals Inc. ("Synthon") became the first generic manufacturers to seek FDA approval to launch generic Exforge. On October 1, 2007, Par was the first to file an Abbreviated New Drug Application ("ANDA") for the 10/160, 5/160 and 10/320 milligram strengths of amlodipine and valsartan, respectively, while on November 26, 2007, Synthon was the first to file an ANDA for the 5/320 milligram strength. In connection with their applications, Par and Synthon were required to make certain certifications against the three Novartis patents covering Exforge. Both filed "Paragraph III" certifications against U.S. Patent No. 5,399,578 ("the '578 Patent"), which had pediatric exclusivity, stating that they would not seek final FDA approval

until the patent and its related pediatric exclusivity expired on September 21, 2012. With regard to U.S. Patent Nos. 6,294,197 (“the ‘197 Patent”) and 6,395,728 (the ‘728 Patent), both Par and Synthon filed “Paragraph IV” certifications, stating that those two patents were invalid and/or not infringed by Par’s and Synthon’s proposed generics.

5. **Par and Synthon were eligible for 180 days of generic exclusivity.** As the first generic filers, and as a result of these certifications, Par and Synthon were each eligible for 180-days of generic marketing exclusivity, with Par eligible for exclusivity for the 10/160, 5/160, and 10/320 mg strengths and Synthon eligible for exclusivity for the 5/320 mg strength. Significantly, though, neither Par nor Synthon could prevent Novartis from selling or licensing its own generic (referred to as an “authorized generic” or “AG”). Brand companies frequently launch or license authorized generics, particularly during a first generic filer’s 180-day exclusivity period, in an effort to prevent the massive loss of revenue a brand suffers when generics enter the market. The brand’s authorized generic typically takes up to 50% of generic sales away from the first generic filer. In effect, an authorized generic permits the brand to recapture some of the sales that it otherwise would have lost to the first generic filer. On March 19, 2010, the FDA granted tentative approval to Par’s generic version of Exforge. And on April 15, 2010, the FDA granted tentative approval to Synthon’s generic version of Exforge. On December 30, 2011, Par acquired Synthon’s rights for generic Exforge in the 5/320 mg and 10/320 mg strengths. As a result, Par held 180-day exclusivity for all strengths of generic Exforge. On March 28, 2013, the FDA granted final approval to all strengths of Par’s generic Exforge.

6. **Novartis does not sue to enforce its patents.** Despite receiving notice that Par and Synthon intended to manufacture generic Exforge before the ‘197 Patent and ‘728 Patent

expired, Novartis did not file a lawsuit against Par or Synthon for infringement of those patents within the 45-day time period set forth in the statute that triggers an automatic 30-month stay of ANDA approval. Upon information and belief, Novartis did not initiate such litigation because it believed its patents were weak and/or likely be found invalid.

7. **Unlawful pay-for-delay agreement.** Rather than compete with new generic drugs on the market or sue to protect its patent rights, Novartis entered into the Anticompetitive Agreement with Par to delay entry of generic Exforge to the market. As part of the Anticompetitive Agreement, (1) Par agreed not to compete in the Exforge market until September 30, 2014, and (2) Novartis agreed not launch an authorized generic (“AG”) version of Exforge from September 30, 2014 to March 30, 2015. Novartis’s no-AG promise was worth hundreds of millions of dollars in additional sales to Par during its 180-day exclusivity period; sales that would have gone to Novartis had it launched an authorized generic. This two-faceted Anticompetitive Agreement had one ultimate effect: it drove the price of Exforge, and later its generic equivalent, to an artificially high, anticompetitive level by both extending Novartis’s monopoly in the Exforge market and eliminating any generic competition for Par’s generic product for six months.

8. **Delay of generic entry.** In the absence of this pay-for-delay agreement, Novartis and Par each would have launched a generic version of Exforge as early as September 21, 2012 (the day the ‘578 Patent expired), and, in any event, well before September 30, 2014, the date before which Par agreed not to enter the market. Additional generics would have launched six months later, after Par’s 180-day exclusivity period expired. The availability of these additional generics to the market would have continued to drive prices down to the benefit of all drug

purchasers. Novartis's sales of Exforge in the United States exceeded \$420 million annually, prior to the entry of generic competition.

9. **Injury to the class.** As a result of Defendants' unlawful pay-for-delay agreement, drug purchasers likely paid hundreds of millions of dollars in overcharges as Novartis continued to sell Exforge at supra-competitive prices without competition for an additional two years past September 2012. In the absence of this unlawful agreement, Par would have entered the market earlier than September 2014, ending Novartis's monopoly and bringing competition and lower prices to consumers of fixed combination products comprising amlodipine and valsartan, as well as to third-party payors who reimburse all or part of the purchase price of Exforge and its generic equivalents.

10. To redress the economic injury Defendants caused, Plaintiff, on behalf of itself and all others similarly situated, seeks damages under state antitrust, consumer protection, and common laws.

III. JURISDICTION AND VENUE

11. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds \$5,000,000, and at least one Class Member (hereinafter defined) is a citizen of a state different from that of one of Defendants.

12. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

13. Venue is appropriate within this District under 28 U.S.C. §1391(b). Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. Defendants' conduct, as described in this complaint, was within the flow of, was intended to, and

did have a substantial effect on, the interstate commerce of the United States, including in this District.

14. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. THE PARTIES

15. Plaintiff Turlock Irrigation District is a consumer-owned, self-funded, not-for-profit irrigation district organized under the laws of the State of California. Plaintiff is headquartered at 333 East Canal Drive, Turlock, California. Plaintiff provides health benefits, including prescription drug benefits, to eligible employees. During the Class Period (hereinafter defined), Plaintiff purchased and paid for some or all of the purchase price of Exforge and/or its AB-rated generic equivalents, thereby suffering injury to its business and property. Plaintiff paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct.

16. Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a corporation organized and existing under the laws of the State of Delaware. Novartis's principal place of business is at One Health Plaza, East Hanover, New Jersey 07936. Novartis is a subsidiary of Novartis AG. It is also the NDA holder as well as a distributor for the prescription drug Exforge. Novartis Pharmaceuticals Corporation has locations in New York, New Jersey and California. As the pharmaceuticals unit of Novartis Corporation and Novartis AG, Novartis Pharmaceuticals

Corporation develops, manufactures, sells, and markets Novartis Corporation's and Novartis AG's drugs in the United States.

17. Defendant Par Pharmaceutical, Inc. d/b/a Par Pharmaceutical ("Par") is a corporation organized and existing under the laws of the State of New York and having its principal place of business at 6 Ram Ridge Road, Chestnut Ridge, New York, 10977. Par principally develops, manufactures, and markets generic versions of brand name drugs. It is also the holder of the ANDA for generic Exforge and was responsible for manufacturing and distributing generic Exforge.

18. Endo Pharmaceuticals, Inc. is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania, 19317. On September 28, 2015, Endo completed an acquisition of Par Pharmaceutical, Inc. and is therefore the successor in interest to Par Pharmaceutical, Inc. Post-acquisition, Endo combined legacy Par Pharmaceutical, Inc. with its existing generics subsidiary, Qualitest Pharmaceuticals, naming the segment Par Pharmaceutical, Inc. d/b/a Par Pharmaceutical.

19. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged in this complaint, and were authorized, ordered, or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, and/or ostensible authority of Defendants.

V. REGULATORY FRAMEWORK

A. The Regulatory Structure for Approval and Substitution of Generic Drugs.

20. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”),¹ a manufacturer that creates a new drug must obtain approval from the Food and Drug Administration (“FDA”) to sell the product by filing a NDA.² Complete NDAs include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.³

21. When the FDA approves a brand manufacturer’s NDA, the manufacturer may cause the FDA to list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the “Orange Book”) certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patent(s). A brand manufacturer has 30 days in which to list patents issued after approval of an NDA in the Orange Book in order for the patent to be considered timely filed.⁴

22. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the authority or resources to verify the manufacturer’s representations for accuracy or trustworthiness and relies completely on the manufacturer’s truthfulness about the validity and applicability of any Orange Book-listed patents.

¹ Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 *et seq.*).

² 21 U.S.C. §§ 301-392.

³ 21 U.S.C. § 355(a), (b).

⁴ 21 U.S.C. § 355(b)(1), (c)(2).

1. The Hatch-Waxman Amendments.

23. In 1984, Congress modified the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a generic manufacturer to file an ANDA with the FDA that relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA. An ANDA filer need demonstrate only that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the bloodstream at a similar rate over a similar period of time are expected to be equally safe and effective. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

24. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

25. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled \$21.6 billion; by 2013, total prescription drug revenues had climbed to more than \$329.2 billion, with generics

accounting for 86% of prescriptions.⁵ When a generic form is available, generics are dispensed approximately 95% of the time.⁶

2. ANDA paragraph IV certifications.

26. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- a. That no patent for the brand has been filed with the FDA (a “paragraph I certification”);
- b. That the patent for the brand has expired (a “paragraph II certification”);
- c. That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a “paragraph III certification”); or
- d. That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a “paragraph IV certification”).⁷

27. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of 30 months, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the

⁵ See IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013*, 30, 51 (2014).

⁶ *Id.* at 51.

⁷ 21 U.S.C. § 355(j)(2)(A)(vii).

generic manufacturer's ANDA. Until one of those conditions is met, the FDA may grant "tentative approval" but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

3. The first filer's 180-day exclusivity period.

28. Generics may be classified as (i) first filer, (ii) later generic filers, or (iii) authorized generics.

29. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer ("first filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.⁸ That is, when a first filer submits a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first generic has been on the market for 180 days.

30. The 180-day window is often referred to as the first filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer, because a brand manufacturer (such as Novartis) can launch an authorized generic ("AG") at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry to recoup some of the sales they would otherwise have lost.

⁸ 21 U.S.C. § 355(j)(5)(B)(iv), (D).

31. The Supreme Court has recognized that “this 180-day period of exclusivity can prove valuable, possibly ‘worth several hundred million dollars’” to the first filer.⁹

32. A first filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

B. The Competitive Effects of AB-Rated Generic Competition.

33. AB-rated generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic manufacturer. This discount typically increases to 50%-80% (or more) when multiple generic competitors compete in the sale for a given drug. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers.

34. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use facilitate both rapid price decline and rapid sales shift from brand to generic purchasing following the launch of AB-rated generic. Once a generic hits the

⁹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. The Federal Trade Commission (“FTC”) has found that, on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.¹⁰

35. Generic competition enables all end-payor purchasers of a drug to purchase generic versions of the drug at substantially lower prices.

36. Until a generic version of the brand enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can therefore continue profitably to charge supra-competitive prices. Brand manufacturers, such as Novartis, are well aware that generic entry leads to rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopolies for as long as possible, sometimes resorting to illegal means to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

37. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.¹¹ Because state substitution laws often require that pharmacists fill brand prescriptions with an available AB-rated generic, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue.

¹⁰ See FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumersbillions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> (“FTC Pay-for-Delay Study”).

¹¹ FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact ii-iii, vi, 34 (2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-longterm-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impactreport-federal-trade-commission.pdf> (“FTC 2011 AG Study”); FTC Pay-for-Delay Study, at 1.

38. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market, though the brand's AG can be, and often is, on the market during the 180-day exclusivity period. Without competition from other generics, during the 180-day exclusivity period a first filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

39. Once the second wave of generic competitors enter the market, after the first filer's 180-day exclusivity period ends, the competitive process accelerates, multiple generic manufacturers compete vigorously with each other over price, and the price of generics is driven down toward marginal manufacturing costs.¹²

40. According to the FDA and the FTC, the greatest price reductions happen after the 180-day exclusivity period ends, when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

41. In a 2011 report by the FTC issued at the request of Congress, the FTC found that generics captured 80% or more of sales in the first six months.¹³ (This percentage erosion of brand sales holds regardless of the number of generic entrants.) In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so

¹² See, e.g., Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311 (2000).

¹³ FTC 2011 AG Study, at 66-67.

because, “[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.”¹⁴

42. Generic competition enables Plaintiff and all members of the proposed Class to purchase generic versions of a drug at substantially lower prices.

3. Brand manufacturers are incentivized to sell an AG when facing generic entry.

43. Authorized generics, like other generics, compete on price.

44. A brand manufacturer may sell an AG at any time. An AG is chemically identical to the brand but sold as a generic, typically through either the brand manufacturer’s subsidiary (if it has one) or a third-party distributor. An AG is essentially the brand product in a different package but sold at a lower price.

45. Early in the life of the patents pertaining to a branded drug, the brand manufacturer has little incentive to sell an AG—doing so would simply cannibalize sales from the more profitable brand product. But when the prospect of generic competition arises, the brand manufacturer’s incentive to sell an AG increases.

46. One study notes that “pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed ‘authorized generics.’”¹⁵

¹⁴ See FDA, *Generic Drugs: Questions and Answers*, <http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm> (last visited Jan. 11, 2018).

¹⁵ Kevin A. Hassett & Robert J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 SONECON (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

47. Brand manufacturers sometimes begin selling AGs before the first filer generic enters the market so they can secure multiyear purchase contracts with direct purchasers and load the generic pipeline at the expense of the first filer generic.

48. Competition from an AG substantially reduces drug prices and the revenues of the first filer generic (especially during the 180-day exclusivity period).¹⁶ A study analyzing three examples of AGs found that “[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand.”¹⁷

49. The FTC found that AGs capture a significant portion of sales, reducing the first filer generic’s revenues by about 50% on average.¹⁸ The first filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

50. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic’s 180-day exclusivity period. All drug industry participants recognize this. PhRMA, a branded drug industry trade group, recognizes it.¹⁹ Generic companies recognize it.²⁰ So do brand companies.²¹

¹⁶ Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. L. REV. 175, 189 (2007).

¹⁷ Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers’ Welfare*, 26 HEALTH AFFAIRS 790, 796 (2007).

¹⁸ FTC 2011 AG Study, at 139.

¹⁹ PhRMA sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting,

C. Pharmaceutical Manufacturers Game the Regulatory Structure to Impair Competition.

51. When they do not face generic competition, brand manufacturers can usually sell the branded drug far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins—without losing so many sales to competitors that the higher price becomes unprofitable—is what economists call market or monopoly power. When generics enter the market, however, they quickly take 80% or more of the unit sales. And because when multiple generics are in the market, the competition between the generics drives their prices to near the marginal cost of production, this competition puts an end to the brand manufacturer’s market or monopoly power and delivers enormous savings to drug purchasers.

52. A brand manufacturer in the marketplace without competition from generics receives all of the profits on all of the unit sales.

Assessment of Authorized Generics in the U.S. (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

²⁰ One generic manufacturer stated that “[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the ‘pure’ generic during the exclusivity period could be reduced by approximately 60% in a typical scenario.” See FTC 2011 AG Study, at 81. Another generic quantified the fiscal consequences of competing with an authorized generic version of the brand drug Paxil, determining that the authorized generic reduced its first generic’s revenues by two-thirds, or by approximately \$400 million. Comment of Apotex Corp. in Support of Mylan Citizen Petition (Mar. 24, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P=0075-emc00001.pdf>. In 2004, generic company Teva acknowledged that an authorized generic would “severely devalu[e]” its 180-day exclusivity because an authorized generic “effectively transfers much of the profit value from the generic challenger [to the authorized generic]” and “allows the [authorized generic] to seize a significant share of the generic supply chain.” Teva Citizen Petition, Docket No. 2004P-0261/CPI (June 9, 2004), www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf.

²¹ Commenting on Teva’s FDA petition, Pfizer stated: “Teva’s petition [to prevent the launch of an authorized generic] is a flagrant effort to stifle price competition—to Teva’s benefit and the public’s detriment.” Comment of Pfizer at 7, Docket No. 2004P-0261 (June 23, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/062904.htm#04P0261>; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf>.

53. When the brand manufacturer competes against only the first filer generic manufacturer, they enjoy a duopoly—both tend to sell at close to the monopoly price, and make near-monopoly profits.²²

54. When multiple generic manufacturers enter, the brand manufacturer loses most of the unit sales; generic manufacturers sell most of the units but at drastically reduced prices; and competition delivers enormous savings to drug purchasers.

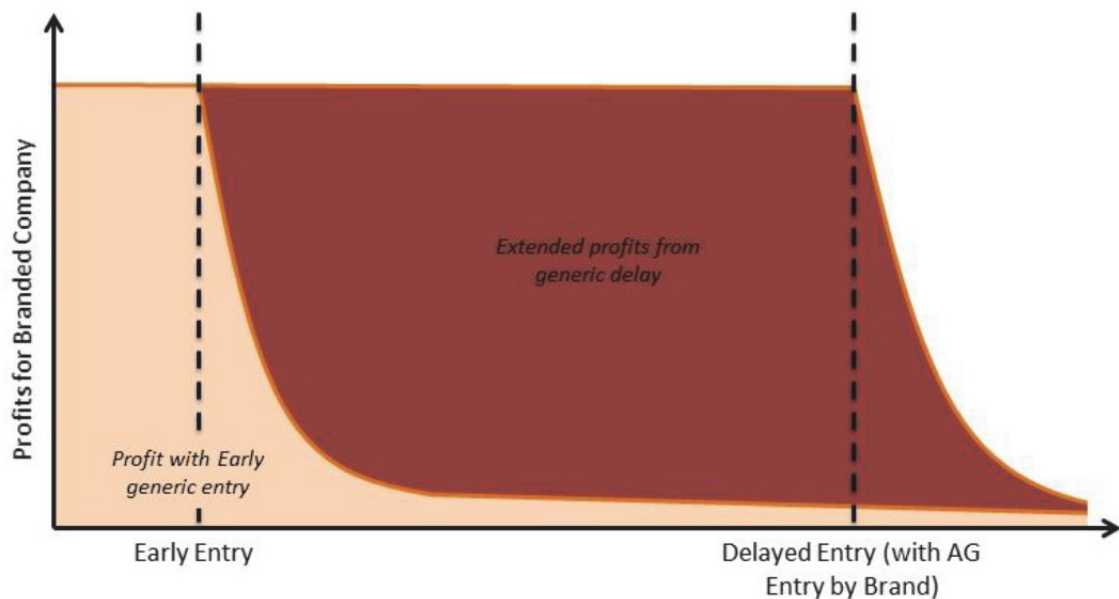
55. Brand and first filer generic manufacturers have a collective interest in preventing this competition from breaking out. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers.

56. To achieve this goal, brand and generic manufacturers sometimes—unlawfully—agree, often but not exclusively in writing, not to compete and instead to split the purchaser savings between themselves.

57. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where the brand manufacturer did not pay-off the generic company to delay generic entry and (ii) a situation where the brand manufacturer conspires with the generic manufacturer to delay generic drug entry. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly.

Figure 1. Impact of Generic Delay on Brand Profits

²² See generally Tony Ellery & Neal Hansen, *Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand* 108 (2012); Benjamin G. Druss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFF. 210, 213-14 (2004).



58. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains through some means. Pay-offs from the brand manufacturer are the means by which brand and generic manufacturers divide between themselves the ill-gotten gains that delayed competition makes possible. These unlawful pay-off deals are often referred to as “pay-for-delay” or “exclusion payment” agreements.

59. The brand manufacturer may choose to pay off only the first filer, even if other generic manufacturers are also lined up to challenge the patents. The first filer’s agreement to delay marketing its drug also prevents other generic manufacturers from marketing their products.

60. Later ANDA filers have more modest financial expectations because they generally anticipate no market exclusivity. By the time they enter the market, there is at least the

brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

61. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

62. When an anticompetitive agreement with the first filer is already in place, however, pursuing litigation becomes less attractive to later ANDA filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement) and that they will have to bear the bulk of the litigation costs themselves.

63. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first filer generic and agree to drop their challenges to the brand manufacturer's patent(s) and stay off the market until after entry by the first filer.

64. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. No-AG agreements enable manufacturers to share the gains from conspiring.

65. In the 1990s, the pay-offs from brand manufacturers often took the form of cash payments to the generic competitor. Since the 2000s, as a result of regulatory scrutiny,

congressional investigations, and class action lawsuits, brand and generic manufacturers have entered into increasingly more elaborate agreements in an attempt to hide pay-offs.

66. One form of pay-off, at issue here, is a no-AG promise. With a no-AG promise, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters the market.

67. Again, the first filer's ANDA exclusivity does not prohibit the brand manufacturer from marketing its AG under the authority of its NDA. The Hatch-Waxman Amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

68. Absent a no-AG promise, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the first generic enters the marketplace. But competition from an AG has a drastically negative effect on the first filer generic's revenues. Competition from an AG typically cuts the first filer's revenues by more than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower—eliminating the duopoly and delivering commensurate savings to drug purchasers.

69. To prevent an AG from causing this substantial loss of revenues and profits, a first filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than make up for the profits it forgoes by not competing with an AG. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic

competition for the first 180 days of marketing. Both manufactures win, but drug purchasers lose.

70. The brand and first filer's reciprocal promises not to compete harm end-payor purchasers like Plaintiff thrice over. The pact delays the first filer's entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. By delaying the first filer's entry, the pact also delays the time when other, later, generics enter, and may discourage their entry altogether. Finally, the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period between the first filer's generic and the brand's AG.

71. For the first filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash.²³ Courts, including those in this Circuit, agree that no-AG agreements are a form of payment actionable under *FTC v. Actavis* and are anticompetitive.

72. For a first ANDA filer (like Par) for a brand drug with millions of dollars in annual sales (like Exforge), the difference between selling a generic without having to compete against an AG and selling in competition with an AG can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

²³ See, e.g., Press Release, FTC, Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics (June 24, 2009), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf>.

73. Figure 2 depicts what happens when a brand manufacturer agrees to a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay, and the purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic):

Figure 2. Impact of No-AG Clause on Brand Profits



VI. EXFORGE CONSPIRACY

A. 1992-2002: Novartis Applies for and Obtains Amlodipine and Valsartan Patents.

74. On December 29, 1992, Novartis filed U.S. Patent Application 998,755, entitled “ACYL Compounds,” which Novartis used to gain exclusivity to manufacture valsartan. The U.S. Patent Office approved the application on March 21, 1995 and issued the ’578 Patent.

75. The ’578 Patent, which disclosed and claimed the chemical compound valsartan, expired on March 21, 2012. As a result of conducting tests in pediatric age groups, the FDA granted Novartis a six-month regulatory exclusivity called pediatric exclusivity which attached to the ’578 Patent and expired on September 21, 2012.

76. On June 18, 1997, Novartis filed a U.S. Patent Application for the '197 Patent. In its patent application, Novartis described that the '197 Patent concerned solid dosage forms comprising (a) valsartan and (b) pharmaceutically acceptable additives suitable for preparing solid oral dosage forms. The U.S. Patent Office approved the application on September 25, 2001.

77. On January 9, 2001, Novartis filed U.S. Patent Application 09/757,413, entitled "Method of Treatment and Pharmaceutical Composition," and described how the invention was developed to treat and prevent diseases related to hypertension, high blood pressure and other cardiac related diseases. The U.S. Patent Office approved the application on May 28, 2002 and issued the '728 Patent.

B. In 2007, Novartis Combines Amlodipine and Valsartan to Create a New Blood Pressure-Lowering Drug.

78. High blood pressure and its consequences affect an estimated one in four adults; that is roughly a billion people worldwide. The disorder is the leading cause of risk-attributable death, accounting for more than 7 million deaths per year. A person dies somewhere in the world from a hypertension-related disease every five seconds.

79. Exforge was the first high blood pressure medication to combine the most commonly prescribed branded high blood pressure medicines in their respective class—Norvasc, the calcium channel blocker amlodipine besylate, and Diovan, the angiotensin-II receptor blocker valsartan. On June 20, 2007, the FDA approved Novartis's NDA for Exforge tablets. Shortly thereafter, Exforge tablets were launched into the U.S. marketplace.

80. Novartis already had intellectual property rights to Diovan, but its plan was to combine the active ingredients in Diovan and Norvasc, the latter of which was a Pfizer product, as soon as Pfizer's patents expired in September 2007. On March 22, 2007, however, the Federal

Circuit invalidated Pfizer's Norvasc patents, paving the way for earlier FDA approval of Novartis's Diovan/Norvasc combination.

81. Novartis claimed that Exforge, the combination of valsartan and amlodipine, offered patients the convenience of a reduced pill load for their hypertension medication, increasing patient adherence.

C. Fall 2007: Par and Synthon File ANDAs for Generic Versions of Exforge.

82. Generic manufacturers Par and Synthon recognized the huge market potential for Exforge and, in or about the fall of 2007, were the first generic companies to file ANDAs with the FDA containing paragraph IV certifications as to certain Exforge patents.

83. Par filed ANDA 90-011 on October 1, 2007, for the 10/160, 5/160, 10/320 milligram strengths of Exforge, and was the first applicant to file a substantially complete application containing a paragraph IV certification for those three strengths, making Par eligible for 180 days of regulatory exclusivity.

84. Synthon filed ANDA 90-144 on November 26, 2007, for the 5/320 milligram strength of Exforge, and was the first applicant to file a substantially complete application containing a paragraph IV certification for the 5/320 mg strength, making Synthon eligible for 180 days of regulatory exclusivity for that strength.

85. Par and Synthon each addressed the Orange Book-listed Novartis patents for Exforge in their ANDA filings as follows: (1) each submitted Paragraph III certifications to the '578 Patent (meaning that they would not seek to market a generic product prior to the expiration of that patent); and (2) each submitted paragraph IV certifications to the '197 and '728 Patents (meaning they sought to enter into the market prior to the expiration of those patents, which they claimed were invalid, unenforceable, and/or would not be infringed by Par's or Synthon's generic products). Therefore, on or shortly after October 1, 2007 and November 26, 2007,

respectively, Par and Synthon disclosed their intentions to market their AB-rated generic products as early as September 21, 2012.

86. Because Par and Synthon were the first companies to file substantially complete ANDAs with paragraph IV certifications, they stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. 355(j)(5)(B)(iv): 180 days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Exforge.

87. After receiving confirmation of receipt from the FDA for their respective ANDAs, Par and Synthon each sent notice to Novartis of their ANDAs containing paragraph IV certifications that included "a detailed factual and legal statement as to why" the '197 and '728 Patents were "invalid, unenforceable, and/or not infringed" by Par's and Synthon's ANDA Products (the "Paragraph IV Notices"). The Paragraph IV Notices each included an offer of confidential access to Par's and Synthon's ANDAs as required under Hatch-Waxman. The Notices gave rise to a cause of action by Novartis for infringement under the Hatch-Waxman Act.

D. 2010: The FDA Grants Tentative Approval of Par's ANDA for the Generic Version of Exforge.

88. On March 19, 2010, the FDA granted tentative approval to Par's ANDA for the generic version of Exforge, indicating its determination that Par's generic Exforge was approvable and satisfied all bioequivalence, chemistry, manufacturing, and controls ("CMC"), and labeling requirements.

E. Novartis Does Not File Suit against Par or Synthon, and, Even If It Had, Novartis Would Have Been Unsuccessful.

89. Within 45 days of receiving Par's Paragraph IV Notices related to the '197 and '728 Patents, the Hatch-Waxman framework permitted Novartis, the patent holder, to sue Par,

the generic manufacturer, for patent infringement. If Novartis had filed suit against Par, an automatic 30-month stay of FDA approval is instituted (commonly called a 30-month Hatch-Waxman stay).

90. After receiving Par's and Synthon's Paragraph IV Notices, Novartis did not file a lawsuit against either Par or Synthon for infringement of the '197 and '728 Patents within the 45-day time period set forth in the statute to trigger a 30-month stay of ANDA approval. Accordingly, no 30-month stay ever went into effect for the Par or Synthon ANDAs.

91. Since Novartis did not sue to enforce its patents, as of March 19, 2010, the only thing preventing Par and Synthon from obtaining final FDA approval and launching its generic Exforge was the last few years of protection afforded by the '578 Patent covering the active ingredient valsartan.

92. The fact that Novartis never sued Par on the '197 or '728 Patents reflects Novartis's belief that those patents did not afford Novartis any right to exclude Par from marketing its generic version of Exforge.

93. Evidence of the weakness of the '197 and '728 Patents includes, but is not limited to:

(a) Par's and Synthon's ability to develop and file ANDAs with Paragraph IV Notices within a few months of FDA's approval of Exforge;

(b) Novartis's decision not to sue for patent infringement to enforce its intellectual property in court; and

(c) The facts set forth above and in Par's and Synthon's Paragraph IV Notices.

1. The '728 Patent was no barrier to generic competition.

94. No valid claim of the '728 Patent was infringed by Par's filing of ANDA No. 90-011 or the manufacture or sale of Par's generic version of Exforge. First, the claims of the '728 Patent are properly construed to be limited to the use of a combination of valsartan and amlodipine for the treatment of hypertension in the limited subset of patients suffering from diabetes and could not have afforded Novartis any right to exclude generic competition beyond that very narrow use. The '728 Patent issued from U.S. Application No. 09/757,413 (the "'413 Application"), which is a divisional of U.S. Application No. 09/349,654 (the "'654 Application").

95. The original claims of the '654 Application broadly recited (1) "[a] method for the treatment or prevention of [a wide variety of different disease states] comprising administering a therapeutically effective amount of a combination" of valsartan and a pharmaceutically acceptable carrier; and (2) "[a] pharmaceutical combination composition comprising" those same ingredients.²⁴

96. The examiner at the U.S. Patent Trademark Office ("PTO"), however, rejected each of those claims as obvious in view of U.S. Patent No. 5,492,904 ("the '904 Prior Art Patent") and the prescribing information for Diovan ("the Prior Art Diovan Literature").²⁵ The U.S. PTO examiner noted that the '904 Prior Art Patent taught the combined use of an angiotensin-II antagonist (like valsartan) and a calcium channel blocker (like amlodipine) "teach[es] pharmaceutical compositions which comprise an angiotensin-II antagonist and a calcium channel blocker of the type presently claimed which are useful in the treatment of

²⁴ '654 Application at 11.

²⁵ Office Action dated May 25, 2000.

hypertension and congestive heart failure. . . [and] that the compositions may comprise from 10 to 300 mg of the desired calcium channel blocker and from 1 to 100 mg of the angiotensin-II antagonist.”²⁶ The U.S. PTO examiner acknowledged that the ’904 Prior Art Patent did not reach valsartan but noted that the Prior Art Diovan Literature “disclose[d] that valsartan was a well-known angiotensin-II antagonist.”²⁷ Accordingly, the examiner deemed the originally-claimed subject matter to be obvious.²⁸

97. The applicants for the ’654 Application amended their method of use claim 1 by deleting the broad recitation of disease conditions and narrowing it to the treatment of “hypertension *associated with diabetes*.”²⁹ Thereafter, the ’654 Application issued as United States Patent No. 6,204,281.

98. The ’413 Application was filed as a divisional application on January 9, 2001, along with a preliminary amendment whose claims were similar to those that had been originally filed in the ’654 Application. The U.S. PTO examiner rejected the claims pending in the ’413 Application as obvious for the same reason he had rejected the claims in the ’654 Application.³⁰ In response to the rejection, and consistent with their amendment to the ’654 Application, the applicants limited claim 1 of the ’413 Application to the treatment of “hypertension associated with diabetes.”³¹ In explaining why the amendment would overcome the examiner’s obviousness rejection, which applied to all pending claims, including the method claims, the applicants

²⁶ *Id.* at 2.

²⁷ *Id.*

²⁸ *Id.* at 3.

²⁹ Amendment After Final Rejection dated October 20, 2000 at 1-2 (emphasis added).

³⁰ April 27, 2001 Office Action at 3.

³¹ Amendment dated July 25, 2001 at 3.

argued that they had shown unexpected results in the treatment of diabetes.³² Thus, while the “composition of matter” claims did not refer explicitly to diabetes, the applicants’ argument was premised on the view that those claims were also limited to the use of the claimed pharmaceutical composition in patients suffering from diabetes.³³

99. The U.S. PTO examiner nevertheless again rejected the claims.³⁴ In response, the applicants further amended the claims to limit them to the use of valsartan with amlodipine. In doing so, they again made clear that both the method of use and composition of matter claims should be viewed as limited to the use in the “treatment of hypertension associated with diabetes.”³⁵

100. Par was not seeking FDA approval to market its product for the treatment of hypertension associated with diabetes, and therefore its ANDA did not infringe on the ’728 Patent.

101. In addition, the claims of the ’728 Patent, had it been challenged, would likely have been declared invalid in view of the prior art. The ’904 Prior Art Patent was issued on February 20, 1996, more than three years before the earliest possible effective filing date of the ’728 Patent. The ’904 Prior Art Patent is also related to hypertension related with diabetes. Specifically, it teaches that “[t]he combinations of this invention can be administered for the treatment of hypertension” and that the “[p]harmaceutical compositions of the invention may contain from 10 to 300 mg of the desired calcium channel blocker and 1 to 100 mg of the angiotensin-II receptor antagonist per unit dose one or more times daily.” ’904 Prior Art Patent at

³² *Id.* at 4.

³³ *Id.* (“Claims 1-9 have been rejected Applicants respectfully traverse this rejection. *The claims are now directed to hypertension associated with diabetes.*”) (Emphasis added).

³⁴ Office Action dated August 1, 2001.

³⁵ Amendment After Final Rejection dated September 24, 2001.

4:4-5 and 44-48. The '904 Prior Art Patent also references certain disease states involving “diabetic” conditions. *Id.* at 3:56-4:3.

102. Although the '904 Prior Art Patent does not explicitly reference valsartan, that is unsurprising. The patent application that issued as the '904 Prior Art Patent was filed on July 28, 1994, whereas the prior art '578 Patent disclosing valsartan did not issue until March 21, 1995. Thus, the '904 Prior Art Patent was filed before valsartan was publicly disclosed by the '578 Patent. As soon as the '578 Patent was issued and disclosed valsartan, however, it would have been obvious to use valsartan as the angiotensin-II receptor antagonist in the combination treatment taught by the '904 Prior Art Patent.

2. Par's ANDA does not infringe on the '197 Patent.

103. As a matter of law, the claims of the '197 Patent cannot cover generic versions of Exforge that contain 35% or less by weight valsartan under the doctrine of equivalents. First, “[a] doctrine of equivalents theory cannot be asserted if it will encompass or ‘ensnare’ the prior art.” Here, the '578 Patent is prior art to the '197 Patent and discloses a tablet that is 35.7% by weight valsartan.³⁶ Any doctrine of equivalents theory that encompassed a compressed solid dosage form having 35% or less valsartan would therefore improperly cover the prior art. Second, “[i]f a theory of equivalence would vitiate a claim limitation . . . then there can be no infringement under the doctrine of equivalents as a matter of law.”³⁷ Here, allowing a claim limitation that requires solid dosage forms comprising “more than” 35% by weight valsartan to cover solid

³⁶ '578 Patent at 63:24-52 (example 93).

³⁷ *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998); *see also Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (“[T]o allow what is undisputedly a minority (i.e., 47.8%) to be equivalent to a majority would vitiate the requirement that the ‘first and second longitudinal strips of adhesive . . . extend the majority of the lengths of said longitudinal marginal portions.’”).

dosage forms having “less than” 35% by weight valsartan would vitiate a claim limitation and would therefore be improper.

104. In addition, had Par or Synthon challenged the relevant claims of the '197 Patent, a court would like have found them invalid. The earliest effective filing date for the '197 Patent is June 18, 1997, and therefore, the '578 Patent that issued on March 21, 1995 is prior art to the '197 Patent. Claim 1 of the '197 Patent, for example, recites the following:

1. A compressed solid dosage form comprising a) an active agent containing an effective amount of Valsartan or a pharmaceutically acceptable salt thereof; and, b) at least one pharmaceutically acceptable additive wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid dosage form.

'197 Patent at 10:22-30. The '578 Patent anticipates this claim, thereby rendering it invalid. '578 Patent at 63:25-52 (example 93). More specifically, the prior art '578 Patent teaches a tablet (*i.e.*, a compressed solid dosage form) comprising 35.7% valsartan and a number of pharmaceutically acceptable additives including, for example, lactose. *Id.*

105. The U.S. PTO examiner apparently did not understand that example 93 of the '578 Patent related to valsartan. Valsartan is a generic name for the chemical compound (S)-N-(1-carboxy-2-methylprop-1-yl)-N-pentanoyl-N-[2'-(1H-tetrazol-5-yl)-biphenyl-4-ylmethyl-] amine. The '578 Patent does not use the term “valsartan” but rather referred to the compound by its chemical name. Had the examiner understood that that example 93 of the '578 Patent referred to valsartan, he would have rejected claim 1 under 35 U.S.C. § 102.

106. When the examiner rejected the claims based on a different prior art reference, the applicants made arguments that could not have been made had the examiner appreciated example 93 of the '578 Patent.

107. Novartis knew Par and/or Synthon would have won a patent infringement lawsuit had Novartis filed one. Thus, since it had weak patent claims, Novartis was desperate to avoid an adverse ruling on its patents.

F. 2011: Novartis Enters into an Agreement with Par.

108. Instead of suing Par, Novartis entered into the Anticompetitive Agreement with Par, whereby Par would abandon its efforts to launch at the earliest possible date after the expiration of the '578 Patent and instead would launch no earlier than September 30, 2014, almost exactly two years after expiry of the '578 Patent. The Anticompetitive Agreement also provided that Novartis would not launch an AG for the first six months after Par's entry into the generic Exforge market.

109. But-for the Agreement, Par would have been ready, able, and willing to launch generic Exforge as early as September 21, 2012, but no later than March 28, 2013, and would have communicated as much to the FDA and requested final approval for its ANDAs well in advance of September 21, 2012. Par would have received final approval from FDA upon the expiry of the exclusivities associated with the '578 Patent on September 21, 2012.

110. By 2009, Exforge was already generating hundreds of millions of dollars per year in revenues for Novartis. Losing a substantial portion of that revenue stream upon expiry of the '578 Patent—as Novartis would have if the '197 and '728 Patents were held by a court to be invalid, unenforceable, or not infringed, or if Par launched upon final FDA approval after expiry of the '578 patent—would have drastically affected Novartis's profits. Thus, Novartis had enormous incentives to avoid patent infringement litigation and to avoid competition from Par by entering into the Anticompetitive Agreement.

111. Important details of the Anticompetitive Agreement were not disclosed until years after it was reached. For example, a January 2012 analyst day presentation by Par lists a

“Synthon/Exforge” “Business Development” arrangement in 2011. Additionally, Par’s 10-K for the fiscal year ending December 31, 2011 states, “On November 30, 2011, we entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc., and on December 30, 2011, we closed on our acquisition, of Synthon’s ANDA for amlodipine besylate and valsartan (5 mg/320 mg and 10 mg/320 mg) fixed dose combination tablets, a generic version of Exforge, for \$9,600 thousand. *Under the terms of a separate license agreement with Novartis Pharmaceuticals Corporation, we have a certain launch date in October 2014.*” (Emphasis added). Similarly, Novartis’s 20-F for the fiscal year ending December 31, 2011 states “In the US, under a license agreement with a generics manufacturer, the product [Exforge] is expected to face generic competition beginning in October 2014.”

1. The Anticompetitive Agreement was a payment to Par from Novartis

112. For Novartis, the benefits of the no-AG agreement were enormous. While it would forgo six months of profits on an authorized generic, in turn it would enjoy more than two years of monopoly profits selling much more expensive and profitable branded Exforge.

113. The Anticompetitive Agreement was entered into at some time before 2011. That agreement delayed Par’s generic entry until September 30, 2014.

114. The Anticompetitive Agreement benefitted Par by guaranteeing that it would be the sole generic on the market during the 180-day exclusivity period, even if it started as early as September 21, 2012 with the expiration of the ’578 Patent. This more than doubled Par’s anticipated sales revenues in the exclusivity period because: (1) Par would capture all or substantially all of the sales that would have gone to the AG, and (2) Par would be able to charge significantly higher prices for its generic product without price competition from the AG. In addition, Par also benefited by delaying its launch of generic Exforge from September 21, 2012

to September 30, 2014 because Novartis could continue raising prices during that time, making the market more lucrative to divide once Par did enter.

115. By 2011, when Defendants entered into the Anticompetitive Agreement, other than the expiration of the '578 Patent, which was set to expire on September 21, 2012, no other impediments existed to the prompt approval and launch of generic Exforge. First, Par's ANDA had already received FDA tentative and final approval. Second, no other patents held by Novartis would forestall generic entry. Third, as evidenced by Par's ANDA and other announcements it made, Par would be ready and able to launch a generic Exforge product by September 21, 2012.

116. Absent the pay-for delay agreement between Novartis and Par, generic entry would have occurred much sooner than it did—as early as September 21, 2012—on a date to be determined by the jury at trial.

117. Without the Anticompetitive Agreement, several additional generics would have come to market after Par's 180-day exclusivity ended, as early as March 21, 2013, and in any event much earlier than March 30, 2015.

118. In the absence of the Anticompetitive Agreement, Novartis would have launched its authorized generic version of Exforge at or around the same time that Par launched its generic as early as September 21, 2012.

2. The value of the Anticompetitive Agreement to Novartis and Par.

119. With generic entry into the Exforge market in September 2012, Novartis would have lost about 80% of its branded sales. Without generic entry, it kept all those sales and continued to enjoy those branded sales for an additional two years.

120. Because Par was the first ANDA filer, its agreement not to launch generic Exforge until September 2014 created a competition bottleneck wherein no other generic company could market a generic Exforge product until 180 days after Par launched its generic

product. By acting in concert with Par to create this bottleneck, Novartis maintained its monopoly on Exforge for two years longer than it otherwise would have.

121. Determining the value to Novartis of the Anticompetitive Agreement is a matter of estimating the additional branded sales it enjoyed during that two-year delay compared to the sales it would have made (a) from the reduced sales of branded Exforge from September 2012 to March 2015, plus (b) the sales of its authorized generic during the same two-and-a-half-year period.

122. Determining the value of the no-AG agreement from Par's perspective requires estimating the additional sales Par made during the six-month generic exclusivity period in 2014-2015 compared to the sales it would have made in the first six months of generic competition starting in September 2012 when, without the benefit of the no-AG agreement, it would have faced competition from Novartis's authorized generic.

123. Under competitive conditions, the calculation of Par's sales during the first six months of generic competition starting, in September 2012, is identical to the calculation for Novartis's AG during this period, because the same assumptions apply to Par's generic as to Novartis's.

124. Under the anticompetitive conditions of the no-AG promise, however, Par stood in a far better position financially. It (a) got 100% (not 50%) of the generic sales in the first six months of generic launch (because there was no authorized generic taking market share); (b) was able to sell that generic during those months for about 90% (not 50%) of the branded price (because there was no authorized generic driving down price); and (c) was able to bring its generic product to a market that had grown in size over the two-year delay period. Indeed, by 2014, annual sales of branded Exforge had grown to over \$400 million.

125. Thus, the no-AG provision represented a very large payment to Par. Specifically, as early as May 2006, financial analysts and media were projecting annual peak sales for Exforge of \$500 million. During Novartis AG's third quarter, 2007 earnings call, Thomas Ebeling, the CEO of its pharma division, expressed optimism that Exforge would become a "blockbuster drug" in the United States, which is an industry designation for drugs that reach \$1 billion in sales. By 2014, Novartis's annual Exforge sales indeed exceeded \$400 million. Using the most conservative of these numbers, Defendants could assume that 6 months of sales would generate revenue of at least \$200 million ($6/12 \times \400 million).

126. Since the first generic is generally expected to take 80% (or more) of the brand sales, approximately \$160 million worth of brand sales would be converted to the generic ($\$200 \text{ million} \times 0.8$). With only one generic on the market, the generic is typically priced at 90% of the brand, which would result in generic sales of approximately \$144 million ($\$160 \text{ million} \times .9$).

127. Thus, the sales revenue during the 180-day exclusivity period that would reasonably have been anticipated by Par under the Anticompetitive Agreement would be approximately \$144 million.

128. Par's expectations would have differed dramatically if Novartis had not promised to refrain from competing with its own AG. According to an FTC study of the dynamics of authorized generic entry during the 180-day generic exclusivity period, the addition of an AG drives the average generic price down to 52% of the brand price.³⁸

129. Thus, while the generics would still take 80% of brand sales, or \$160 million, the generic sales value would drop to \$83.2 million ($\$160 \text{ million} \times 0.52$). And, it would reasonably

³⁸ <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>.

be expected that those sales would be split evenly between Par's generic and Novartis's AG. Thus, without the no-AG Agreement, Par's expected share of the revenue from sales of generic Exforge during the first 6 months would be approximately \$41.6 million (\$83.2 million x .5).

130. As a result, the expected value at the time of the Anticompetitive Agreement to Par of having no-AG versus facing competition from an AG would have been at least approximately \$102.4 million (\$144 million - \$41.6 million). Thus, Novartis's agreement to not launch an AG for 6 months constituted a payment to Par of \$102.4 million or more. The value of this payment to Par was no different than if Novartis had handed \$102.4 million to Par in cash.

G. 2013: The FDA Grants Final Approval.

131. On March 28, 2013, the FDA granted final approval to Par's ANDA for a generic version of Exforge.

H. 2014: Par Launches a Generic Version of Exforge; Novartis Does Not.

132. On September 30, 2014, Par launched its generic Exforge, which, at that time, was the first and only generic form of Exforge available in the United States.

133. From September 30, 2014 through March 30, 2015, Par's generic Exforge product was the only generic version of Exforge sold in the U.S. market.

134. From September 30, 2014 through March 30, 2015, Novartis was permitted to sell a generic version of Exforge in competition with Par's generic Exforge product. However, Novartis did not launch an authorized generic version of Exforge during Par's 180-day exclusivity period.

135. Novartis and its generic subsidiary Sandoz, Inc. frequently launch authorized generics. Indeed, the FTC has found that, in the time period from 2001 to 2008, only three companies launched more authorized generics than Novartis.³⁹

136. Novartis has stated in public SEC filings that “[t]he company that launches an authorized generic typically launches its product at the same time as the generic exclusivity holder.”

137. On information and belief, Novartis has launched at least sixteen authorized generics between 2005 and 2016, including authorized generic versions of Exelon, Famvir, Focalin XR, Lescol XL, Lopressor HCT, Lotrel, Patanase, Patanol, Ritalin, Ritalin SR, Sandostatin, Tegretol XR, Tobi, Tobradex, Trileptal, and VivelleDot.⁴⁰

138. It is economically rational for a brand manufacturer that intends to launch an AG to do so contemporaneously with the first ANDA filer’s launch. The Supreme Court has observed that “the vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.” *Actavis*, 133 S. Ct. at 2229.

139. Upon information and belief, Novartis would have launched an authorized generic version of Exforge upon market entry by Par in the absence of the Anticompetitive Agreement here.

140. Until Novartis failed to launch an AG upon market entry by Par in September of 2014, it was not clear that Novartis intended to forgo such a launch, as important details of the

³⁹ See FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (Aug. 2011), available at <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf> at p. 16 (“For each company, the graph includes all AGs marketed pursuant to the company’s NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.”).

⁴⁰ See FDA’s Listing of Authorized Generics as of March 28, 2018, available at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605>.

license agreement between Novartis and Par were concealed. As set forth above, the six months of delay from Par's launch in Novartis's launch of an AG constituted consideration to Par.

141. Even with the most conservative estimates, the payment flowing from Novartis to Par via the Anticompetitive Agreement not to compete with an AG, thereby foregoing the 30-month stay, and Novartis not suing for patent infringement, had a cash value in excess of a hundred million dollars. The payment was to induce Par to stay out of the market for Exforge and its generic equivalents in return for sharing monopoly profits among Defendants.

I. March 2015: 180 Days After Par's Generic Exforge Launches, More Generics Launch.

142. On or about on March 30, 2015—the day Par's period of exclusivity expired—Mylan, N.V. ("Mylan"), Teva Pharmaceutical Industries, Ltd. ("Teva"), Torrent Pharms, Ltd. ("Torrent"), Novel Labs, Inc. ("Novel") and Lupin Pharmaceuticals, Inc. ("Lupin") received final approval from the FDA and launched generic versions of Exforge.

143. On information and belief, Mylan, Teva, Torrent, Novel, and Lupin launched without a license from Novartis, despite the fact that the '197 and '728 patents had not yet expired. Novartis also would have launched its AG upon Par's launch.

144. According to information available publicly through the FDA, in addition to Par and Synthon, at least eight additional companies filed ANDAs to sell generic Exforge:

Application No.	Company
202713	Alembic Pharms Ltd
206512	Aurobindo Pharma Ltd
205137	Invagen Pharms
090245	Lupin
090483	Mylan Pharms Inc.
202829	Novel Labs Inc
091235	Teva Pharms USA
202377	Torrent Pharms Ltd

145. Also according to information available publicly through the FDA, many of these entities received final approval on or around the end of Par's actual 180-day exclusivity of March 30, 2015.

146. Thus, had Par launched its generic product as early as September 21, 2012, but no later than March 28, 2013, at least one subsequent filer, and likely several, would have obtained final FDA approval and launched its generic equivalent of Exforge immediately upon expiration of Par's 180-day exclusivity period.

147. But for Defendants' ongoing performance under the Anticompetitive Agreement, generic competition for Exforge would have occurred earlier and prices for both branded and generic versions of Exforge would have been lower. Because generic versions of Exforge would have become available as early as September 21, 2012, but no later than March 29, 2013, Plaintiff and other members of the Class would have paid lower prices for Exforge and its generic equivalents. Defendants, by their conduct, have injured Plaintiff and other members of the Class by causing them to pay millions of dollars in overcharges on their purchases of Exforge and its generic equivalents.

VII. ANTICOMPETITIVE EFFECTS AND EFFECTS ON INTERSTATE AND INTRASTATE COMMERCE

148. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Exforge from generic competition. But for the pay-for-delay agreement, Par would have entered the market earlier than September 2014. In addition, upon market entry by Par, Novartis would have begun selling its own less expensive Exforge AG in direct competition with the Par generic. Other ANDA-based Exforge generics—including those marketed by Mylan, Teva, Torrent, Novel, and Lupin—would have followed into the market as early as 180 days after Par's launch. The resulting competition would have forced

decreases in the prices of Exforge, as price competition among the suppliers of branded and generic versions of Exforge would have been intense.

149. But for Defendants' illegal conduct, Plaintiff and members of the Class would have paid less for branded and generic versions of Exforge. Defendants' conduct proximately caused Plaintiff's and the Class's injuries because it forced them to pay hundreds of millions of dollars in overcharges on purchases of branded and generic versions of Exforge.

150. If generic competition for branded Exforge had not been unlawfully delayed, Plaintiff and members of the Class would have paid less for both branded and generic versions Exforge by: (a) substituting their purchases of branded Exforge with less-expensive generic versions of Exforge; and (b) purchasing generic Exforge at lower prices sooner.

151. As a result of the delay in generic competition brought about by Defendants' anticompetitive scheme, Plaintiff and members of the Class paid more for branded and generic Exforge than they would have paid absent Defendants' illegal conduct.

152. Defendants' efforts to restrain competition in the market for branded and generic versions of Exforge have substantially affected both interstate and intrastate commerce.

153. At all material times, Novartis manufactured, promoted, distributed, and sold substantial amounts of branded Exforge in a continuous and uninterrupted flow of commerce across state lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering cheaper generic versions of Exforge to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

154. At all material times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of branded and generic versions of Exforge.

155. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that “[e]very person at every stage in the chain will be poorer” as a result of the anticompetitive price at the top.⁴¹ He also says that “[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level.”⁴²

156. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of branded and generic versions of Exforge to Plaintiff and members of the Class.

157. Defendants’ pay-for-delay agreement enabled Novartis to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent Defendants’ unlawful actions.

158. These prices were inflated as a direct and foreseeable result of Defendants’ anticompetitive conduct.

⁴¹ See Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

⁴² *Id.*

VIII. MONOPOLY POWER AND MARKET DEFINITION

159. The relevant product market is Exforge (in all its forms and dosage strengths) and bioequivalent generic versions of Exforge. The relevant geographic market is the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

160. At all relevant times, Novartis has maintained monopoly power over the market for Exforge and its AB-rated generic equivalents in that it has had the power to maintain the price of Exforge at supracompetitive levels without losing sales.

161. Novartis has monopoly power over the price of fixed combination products comprising amlodipine and valsartan. Such direct evidence of Novartis's monopoly power includes, among other things, the abnormally-high price-cost margins enjoyed by Novartis prior to entry of generic Exforge and Novartis's ability to profitably maintain the price of Exforge well above competitive levels.

162. Novartis's anticompetitive payment to Par demonstrates that Novartis enjoyed market and/or monopoly power with respect to Exforge (in all its forms and dosage strengths) and bioequivalent generic versions of Exforge.

163. A small but significant non-transitory price increase above the competitive level for Exforge by Novartis would not cause a loss of sales sufficient to make the price increase unprofitable.

164. At competitive price levels, Exforge does not exhibit significant positive cross-price elasticity of demand with any product other than AB-rated generic versions of Exforge.

165. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition by reducing output and increasing prices for branded and generic Exforge, throughout the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

166. Other drugs that are not AB-rated to Exforge cannot be substituted automatically for Exforge by pharmacists and do not exhibit substantial cross-price elasticity of demand with respect to Exforge. Thus, they are not economic substitutes for, nor reasonably interchangeable with, Exforge.

167. The existence of other products designed to treat hypertension or other illnesses treated by Exforge has not significantly constrained Novartis's pricing of Exforge.

168. Novartis needed to control only Exforge and its AB-rated generic equivalents, and no other products, in order to maintain the price of Exforge profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Exforge would render Novartis unable to profitably maintain its prices of Exforge without losing substantial sales.

169. Novartis, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

170. Novartis has maintained and exercised the power to exclude and restrict competition to Exforge and AB-rated generics.

171. At all relevant times, Novartis's market share in the relevant market was 100%, implying substantial monopoly power.

IX. CLASS ACTION ALLEGATIONS

172. Plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages on behalf of the following class (the "Class"):

All persons and entities that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Exforge or its AB-rated generic equivalents from Defendants, beginning at least as early as September 21, 2012 until the effects of Defendants' conduct cease ("Class Period"), in the District of

Columbia, Puerto Rico, or any of the following states and commonwealths: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Tennessee, Utah, Vermont, West Virginia, Wisconsin, or Wyoming.

173. The following persons and entities are excluded from each of the above-described proposed Class:

- (d) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;
- (e) All governmental entities, except for government-funded employee benefit plans;
- (f) All persons or entities who purchased Exforge for purposes of resale or directly from Defendants or their affiliates;
- (g) Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);
- (h) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs);
- (i) Pharmacy benefit managers;
- (j) All Counsel of Record; and
- (k) The Court, Court personnel and any member of their immediate families.

174. Members of the Class are so numerous and geographically dispersed that joinder of all members of the Class is impracticable. Plaintiff believes that there are thousands of members of the Class widely dispersed throughout the United States. Moreover, given the costs

of complex antitrust litigation, it would be uneconomic for many Plaintiffs to bring individual claims and join them together. The Class members are readily identifiable from information and records in Defendants' possession.

175. Plaintiff's claims are typical of the claims of members of the Class. Plaintiff and members of the Class were harmed by the same wrongful conduct by Defendants in that they paid artificially inflated prices for branded and generic Exforge and were deprived of the benefits of earlier and more robust competition from cheaper generic equivalents of Exforge as a result of Defendants' wrongful conduct.

176. Plaintiff will fairly and adequately protect and represent the interests of the members of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Class.

177. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation and with experience in class action antitrust litigation involving pharmaceutical products.

178. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual members of the Class because Defendants have acted on grounds generally applicable to the entire class, making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

179. Questions of law and fact common to the Class include:

(a) Whether Novartis unlawfully maintained monopoly power through the Anticompetitive Agreement;

- (b) Whether Defendants' scheme, in whole or in part, has substantially affected intrastate and interstate commerce;
- (c) Whether Defendants conspired to delay generic competition for Exforge;
- (d) Whether, pursuant to the pay-for-delay agreement, Novartis's promise not to compete against Par's generic product constituted a payment;
- (e) Whether Defendants' Anticompetitive Agreement was necessary to yield some cognizable, non-pretextual procompetitive benefit;
- (f) Whether Novartis's compensation to Par was large and unexplained;
- (g) Whether the pay-for-delay agreement was a bottleneck to further delay generic competition for Par;
- (h) Whether the pay-for-delay agreement harmed competition;
- (i) Whether Defendants' Anticompetitive Agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Class; and
- (j) The quantum of overcharges paid by the Class in the aggregate.

180. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

181. Plaintiff knows of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

X. DEFENDANTS' FRAUDULENT CONCEALMENT TOLLED THE APPLICABLE STATUTES OF LIMITATIONS AND DELAYED ACCRUAL OF PLAINTIFF'S CAUSES OF ACTION

182. Due to Defendants' concealment of the terms of the Anticompetitive Agreement, Plaintiff and members of the Class are entitled to recover damages reaching back beyond any limitations periods otherwise applicable to their claims, because the earliest they could reasonably have learned of Defendants' conspiracy was in September 2014, when Par began selling generic Exforge and Novartis did not respond with an AG.

183. Novartis and Par had earlier disclosed only cursory information about the existence of the Anticompetitive Agreement. Plaintiff and members of the Class had no knowledge of Defendants' unlawful scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence, nor did they have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed, or believe in good faith that a violation had been committed, until September 2014.

184. This is true because the nature of Defendants' scheme was self-concealing and because Defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to conceal, their contract, combination, conspiracy and scheme.

185. Defendants wrongfully and affirmatively concealed the existence of their ongoing conspiracy from Plaintiff and the Class by, among other things:

(a) Concealing the fact of Novartis's agreement not to launch a competing authorized generic Exforge product in exchange for Par's agreement not to market its competing generic product until September 30, 2014; and

(b) Concealing the fact that the purpose of the Agreement was to provide compensation in connection with the September 30, 2014 entry date for Par's generic product.

186. Defendants also concealed from Plaintiff the material terms of the Agreement in their public filing documents with the United States Securities and Exchange Commission. For example, a January 2012 analyst presentation by Par lists a "Synthon/Exforge" "Business Development" arrangement in 2011. And Par's Form 10-K for the fiscal year ending December 31, 2011 stated:

On November 30, 2011, we entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc., and on December 30, 2011, we closed on our acquisition, of Synthon's ANDA for amlodipine besylate and valsartan (5 mg/320 mg and 10 mg/320 mg) fixed dose combination tablets, a generic version of Exforge, for \$9,600 thousand. Under the terms of a separate license agreement with Novartis Pharmaceuticals Corporation, we have a certain launch date in October 2014.⁴³

187. Similarly, Novartis's Form 20-F for the fiscal year ending December 31, 2011 stated: "In the US, under a license agreement with a generics manufacturer, the product [Exforge] is expected to face generic competition beginning in October 2014."⁴⁴

188. It was not until Novartis failed to launch an AG upon market entry by Par in September of 2014 that it became clear that Novartis and Par's Agreement contained a no-AG promise. No amount of diligence could have put Plaintiff on notice of its claim until September 30, 2014 at the earliest.

⁴³ Par Pharmaceutical Companies, Inc., Form 10-K, at F-22, <https://www.sec.gov/Archives/edgar/data/878088/000087808812000027/f201110k2281210amnlolinks.htm>.

⁴⁴ Novartis AG, Form 20-F at 7, <https://www.sec.gov/Archives/edgar/data/1114448/000104746912000354/a2205643z20-f.htm>.

189. Plaintiff had no knowledge of suspicious conduct prior to Novartis's failure to launch an authorized generic upon Par's September 30, 2014 entry of generic Exforge. Their continuing ignorance was not attributable to a lack of diligence on their part.

190. Because Defendants concealed the illegal no-AG term, there was no way to know about it until it transpired.

191. As a result of Defendants' concealment, all applicable statutes of limitations affecting Plaintiff's and the Class's claims have been tolled.

XI. CONTINUING VIOLATIONS

192. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and the members of the Class can recover for damages that they suffered during the limitations period.

193. A cause of action accrued for Plaintiff and the Class each time Plaintiff or members of the Class paid for or reimbursed a purchase of Exforge or its generic equivalent at a supra-competitive price made possible by Defendants' anticompetitive conduct. The September 2014 launch by Par, Novartis's forgoing a launch of an AG at that time, and each sale by Defendants of a product at a supra-competitive price constitute overt acts in furtherance of their anticompetitive scheme. Accordingly, Plaintiff and the Class are entitled to recover all damages on all sales that Defendants made to them at supra-competitive prices.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Conspiracy and Combination in Restraint of Trade under State Law (Against All Defendants)

194. Plaintiff incorporates the preceding paragraphs by reference.

195. Defendants entered into an unlawful pay-for-delay agreement that restrained competition in the market for Exforge and its AB-rated generic equivalents. Their agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

(a) delay entry of generic Exforge in order to lengthen the period in which Novartis's brand Exforge could monopolize the market and make supra-competitive profits;

(b) keep an Exforge AG off the market during Par's 180-day generic exclusivity period, thereby allowing Par to monopolize the generic market for Exforge during that period and allowing Par to make supra-competitive profits;

(c) allocate 100% of U.S. generic Exforge sales to Par during the first 180 days of generic sales; and

(d) raise and maintain the prices that Plaintiff and the Class Members would pay for Exforge to and at supra-competitive levels.

196. Defendants' unlawful agreement harmed Plaintiff and the Class Members as set forth above.

197. There is no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect.

198. Defendants' conduct violated the following state antitrust laws:

(a) Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by the Class Members;

(b) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by the Class Members;

(c) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by the Class Members;

(d) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the Class Members;

(e) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Class Members;

(f) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by the Class Members;

(g) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Class Members;

(h) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the Class Members;

(i) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by the Class Members;

(j) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by the Class Members;

(k) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class Members;

(l) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the Class Members;

(m) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by the Class Members, in that thousands of sales of branded and generic versions of Exforge

took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;

(n) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by the Class Members;

(o) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by the Class Members;

(p) N.Y. Gen. Bus. L. §§ 340, et seq., with respect to purchases in New York by the Class Members;

(q) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by the Class Members;

(r) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by the Class Members;

(s) Or. Rev. Stat. §§ 6.46.705, et seq., with respect to purchases in Oregon by the Class Members;

(t) S.D. Codified Laws Ann. §§ 37-1, et seq., with respect to purchases in South Dakota by the Class Members;

(u) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by the Class Members, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Exforge at Tennessee pharmacies;

(v) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damage Class Members who are either citizens or residents of Utah;

(w) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by the Class Members;

(x) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by the Class Members; and

(y) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by the Class Members, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Exforge at Wisconsin pharmacies.

199. Plaintiff and the Class Members have been injured in their business or property by Defendants' antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Exforge and (2) paying higher prices for branded and generic versions of Exforge than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

200. Plaintiff and the Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

201. Defendants are jointly and severally liable for all damages suffered by Plaintiff and the Class Members.

SECOND CLAIM FOR RELIEF

Monopolization and Monopolistic Scheme under State Law (Against Novartis)

202. Plaintiff incorporates the preceding paragraphs by reference.

203. Novartis has knowingly engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Exforge. The intended and accomplished goal of the scheme was to use exclusionary conduct to delay the ability of generic manufacturers to

launch competing, generic versions of Exforge. Novartis's exclusionary conduct maintained Novartis's monopoly over branded and generic Exforge.

204. Plaintiff and the Class Members have suffered harm as a result of paying higher prices for Exforge and/or its AB-rated generic equivalents than they would have absent Novartis's anticompetitive conduct and continuing anticompetitive conduct.

205. Novartis's conduct violated the following state antitrust laws:

(a) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by the Class Members;

(b) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by the Class Members;

(c) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by the Class Members;

(d) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the Class Members;

(e) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Class Members;

(f) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by the Class Members;

(g) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Class Members;

(h) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the Class Members;

(i) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by the Class Members;

(j) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by the Class Members;

(k) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class Members;

(l) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the Class Members;

(m) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by the Class Members, in that thousands of sales of branded and generic versions of Exforge took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendant's conduct;

(n) N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by the Class Members;

(o) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by the Class Members;

(p) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by the Class Members;

(q) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by the Class Members;

(r) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by the Class Members;

(s) Or. Rev. Stat. §§ 6.46.705, et seq., with respect to purchases in Oregon by the Class Members;

(t) S.D. Codified Laws Ann. §§ 37-1, et seq., with respect to purchases in South Dakota by the Class Members;

(u) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by the Class Members, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Exforge at Tennessee pharmacies;

(v) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damage Class Members who are either citizens or residents of Utah;

(w) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by the Class Members;

(x) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by the Class Members; and

(y) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by the Class Members, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Exforge at Wisconsin pharmacies.

206. Plaintiff and the Class Members have been injured in their business or property by Novartis's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Exforge and (2) paying higher prices for these products than they would have paid in the absence of Novartis's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent and flow from that which makes Novartis's conduct unlawful.

207. Plaintiff and the Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Novartis's anticompetitive conduct

THIRD CLAIM FOR RELIEF

**State Consumer Protection Violations
(Against All Defendants)**

208. Plaintiff incorporates the preceding paragraphs by reference.

209. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and the Class Members were deprived of the opportunity to purchase generic versions of Exforge and were forced to pay higher prices for branded and generic versions of Exforge.

210. For years, there was gross disparity between the price that Plaintiff and the Class Members paid for Exforge compared to what they would have paid for less expensive generic versions of Exforge, which should and would have been available but for Defendants' unlawful conduct.

211. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

**Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")
Florida Stat. §§ 501.201, et seq.**

212. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

213. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

214. Under Florida law, end-payor purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint.

215. Defendants' conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Exforge by unreasonably delaying the entry of cheaper, competing generic versions of Exforge from at least as early as March 2013 continuing through September 2014.

216. This delay was the product of an unlawful pay-for-delay agreement, whereby Novartis agreed not to launch a competing Exforge AG during Par's 180-days of marketing exclusivity.

217. Defendants' conduct preserved Novartis's monopoly over Exforge for an additional five years and stunted the effectiveness of future generic competition. This in turn caused end-payor purchasers of branded and generic versions of Exforge in Florida to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Exforge in Florida and their conduct had a direct and substantial impact on trade and commerce in Florida.

218. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

Massachusetts Consumer Protection Act ("MCPA")
Mass. Gen. L. Ch. 93A, et seq.

219. The MCPA regulates trade and commerce "directly or indirectly affecting the people of this commonwealth." Mass. Gen. L. Ch. 93A § 9(1).

220. Under the MCPA, “Any person, who has been injured by another person’s use or employment of any method, act or practice” that constitutes “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.” Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

221. Defendants’ conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Exforge by unreasonably delaying the entry of cheaper, competing generic versions of Exforge from at least as early as March 2013 continuing through September 2014.

222. This delay was the product of an unlawful pay-for-delay agreement, whereby Novartis agreed not to launch a competing Exforge AG during Par’s 180-days of marketing exclusivity.

223. Defendants’ conduct preserved Novartis’s monopoly over Exforge for an additional five years and stunted the effectiveness of future generic competition. This in turn caused end-payor purchasers of branded and generic versions of Exforge in Massachusetts to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Exforge in Massachusetts, and their conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

**Missouri Merchandising Practices Act (“MMPA”)
Mo. Rev. Stat. 407.020**

224. Under Section 407.020, the MMPA prohibits “[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce.” Mo. Rev. Stat. 407.020.

225. The Missouri Attorney General has defined an “unfair practice” as:

any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att’y Gen. Reg., 15 CSR 60-8.02.

226. Defendants’ conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Exforge by unreasonably delaying the entry of cheaper, competing generic versions of Exforge from at least as early as March 2013 continuing through September 2014.

227. This delay was the product of an unlawful pay-for-delay agreement whereby Novartis agreed not to launch a competing authorized generic version of Exforge during Par’s 180-days of marketing exclusivity.

228. Defendants’ conduct preserved Novartis’s monopoly over Exforge for an additional five years and stunted the effectiveness of future generic competition. This in turn caused end-payor purchasers of branded and generic versions of Exforge in Missouri to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Exforge in Missouri, and Defendants’ conduct had a direct and substantial impact on trade and commerce in Missouri. Upon information and belief, Defendants also directed

advertising and marketing efforts for branded and generic versions of Exforge in Missouri. Accordingly, Defendants' conduct falls within the prohibitions in the MMPA.

FOURTH CLAIM FOR RELIEF

**Unjust Enrichment
(Against All Defendants)**

229. Plaintiff incorporates by reference the preceding allegations.

230. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

231. This claim is pled by Plaintiff and the Class against all Defendants.

232. Defendants have financially benefited from overcharges on sales of branded and generic versions of Exforge, which resulted from the unlawful acts alleged in this Complaint. These overcharges were borne by Plaintiff and the Class Members who purchased and/or reimbursed all or part of the purchase price of branded and generic Exforge. The benefits conferred upon Defendants are substantial and measurable, in that the revenues Defendants have earned due to unlawful overcharges are ascertainable by review of both sales records and the unlawful pay-for-delay agreement itself.

233. Moreover, Novartis's promise not to launch a competing authorized generic version of Exforge during Par's 180-day marketing exclusivity period was inextricably linked to the overcharges that Plaintiff and the Class Members were to pay and thus part of the enrichment of Defendants at the expense of Plaintiff and the Class Members.

234. For years, there was gross disparity between the price that Plaintiff and the Class Members paid for Exforge compared to what they would have paid for less expensive generic versions of Exforge, which should and would have been available but for Defendants' unlawful and inequitable conduct.

235. Defendants repeatedly and continuously received financial benefits at the expense of Plaintiff and the Class Members through each sale of branded and generic versions of Exforge at an inflated price.

236. It would be futile for Plaintiff and the Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to any other person for any of the benefits they received indirectly from Plaintiff and the Class Members.

237. It would be futile for Plaintiff and the Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Exforge, as those intermediaries cannot reasonably be expected to compensate Plaintiff and the Class Members for Defendants' unlawful conduct.

238. The financial benefits that Defendants derived rightfully belong to Plaintiff and the Class Members, which paid anticompetitive prices that inured to Defendants' benefit.

239. It would be inequitable under the unjust enrichment principles of the states listed below for Defendants to retain any of the overcharges that Plaintiff and the Class Members paid for branded and generic versions of Exforge which were derived from Defendants' anticompetitive, unfair, and unconscionable methods, acts, and trade practices.

240. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them into a common fund for the benefit of Plaintiff and the Class Members.

241. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for branded and generic versions of Exforge by Plaintiff and the Class Members.

242. Plaintiff and the Class Members have no adequate remedy at law.

243. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and the Class Members of the opportunity to purchase lower-priced generic versions of Exforge and forced them to pay higher prices for branded and generic versions of Exforge, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

244. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Alabama at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have benefitted at the expense of the Class from revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. It is inequitable for Defendants to accept and retain the benefits received without compensating the Class.

Alaska

245. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Alaska at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefits bestowed upon them by the Class. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Arizona

246. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Arizona at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Exforge or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

Arkansas

247. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Arkansas at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

California

248. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in California at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit

from the Class as a direct result of the unlawful overcharges. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Class.

Colorado

249. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Colorado at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants have benefitted at the expense of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Connecticut

250. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Connecticut at prices that were more than they would have been but for Defendants' actions. Defendants were benefitted in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants have paid no consideration to any other person in exchange for this benefit. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Class.

Delaware

251. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Delaware at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Exforge or its AB-rated generic

equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

District of Columbia

252. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in the District of Columbia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Florida

253. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Florida at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Georgia

254. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Georgia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Hawaii

255. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Hawaii at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Idaho

256. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Idaho at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Illinois

257. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Illinois at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Iowa

258. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Iowa at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by d the Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Kansas

259. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Kansas at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefits bestowed upon them

under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Kentucky

260. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Kentucky at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Louisiana

261. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Louisiana at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Exforge or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no other remedy at law.

Maine

262. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Maine at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Maryland

263. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Maryland at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Massachusetts

264. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Massachusetts at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Michigan

265. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Michigan at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Minnesota

266. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Minnesota at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated and knowingly accepted the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Mississippi

267. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Mississippi at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges. Defendants retain the benefit of overcharges received on the sales of Exforge or its AB-rated generic equivalents, which in equity and good conscience belong to the Class on account of Defendants' anticompetitive conduct.

Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Missouri

268. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Missouri at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class.

Montana

269. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Montana at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Nebraska

270. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Nebraska at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. In justice and

fairness, Defendants should disgorge such money and remit the overcharged payments back to the Class.

Nevada

271. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Nevada at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. Defendants appreciated the benefits bestowed upon them by the Class, for which they have paid no consideration to any other person. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

New Hampshire

272. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in New Hampshire at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Jersey

273. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in New Jersey at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. The benefits

conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from the Class with respect to Defendants' sales of Exforge or its AB-rated generic equivalents. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

New Mexico

274. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in New Mexico at prices that were more than they would have been but for Defendants' actions. Defendants have knowingly benefitted at the expense of the Class from revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

275. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in New York at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by the Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Class. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

276. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in North Carolina at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The Class did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records. Defendants consciously accepted the benefits conferred upon them.

North Dakota

277. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in North Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Exforge or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Oklahoma

278. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Oklahoma at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. The Class has no remedy at law. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

279. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Oregon at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of the benefit bestowed upon them by the Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Pennsylvania

280. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Pennsylvania at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Puerto Rico

281. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Puerto Rico at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Exforge or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Exforge or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

Rhode Island

282. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Rhode Island at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

South Carolina

283. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in South Carolina at prices that were more than they would have been but for Defendants' actions. The benefits conferred upon

Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. Defendants realized value from the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

South Dakota

284. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in South Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing the Class.

Tennessee

285. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Tennessee at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class. It would be futile for the Class to seek a remedy from any party with whom they have privity of contract. Defendants have paid no consideration to any other person for any of the unlawful benefits they received indirectly from the Class with respect to Defendants' sales of Exforge or its AB-rated generic equivalents. It would be futile for The Class to exhaust all remedies against the entities with which the Class has privity of contract

because the Class did not purchase Exforge or its AB-rated generic equivalents directly from any Defendant.

Texas

286. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Texas at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. The circumstances under which Defendants have retained the benefits bestowed upon them by the Class are inequitable in that they result from Defendants' unlawful overcharges for Exforge or its AB-rated generic equivalents. The Class has no remedy at law.

Utah

287. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Utah at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Vermont

288. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Vermont at prices that were more than they would have been but for Defendants' actions. The Class has conferred an

economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants accepted the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Virginia

289. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Virginia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of the benefit bestowed upon them. Defendants should reasonably have expected to repay the Class. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of Exforge or its AB-rated generic equivalents. Defendants have paid no consideration to any other person for any of the benefits they have received from the Class.

Washington

290. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Washington at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

West Virginia

291. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in West Virginia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Wisconsin

292. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Wisconsin at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Wyoming

293. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Exforge or its AB-rated generic equivalents in Wyoming at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants accepted, used and enjoyed the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

XIII. DEMAND FOR JUDGMENT

294. WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully demand that this Court:

(a) Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and declare Plaintiff as the representative of the Class;

(b) Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

(c) Award the Class damages, and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial;

(d) Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

(e) Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIV. JURY DEMAND

295. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Date: July 27, 2018

GRANT & EISENHOFER P.A.

/s/ Robert G. Eisler

Robert G. Eisler

Deborah A. Elman

Chad B. Holtzman

Allison J. McCowan

485 Lexington Avenue

New York, NY 10017

Tel: (646) 722-8500

Fax: (646) 722-8501

reisler@gelaw.com

delman@gelaw.com

choltzman@gelaw.com

amccowan@gelaw.com

HARTLEY LLP

Jason S. Hartley

Jason M. Lindner

550 West C St., Ste 1750

San Diego, CA 92101

Tel: (619) 400-5822

Fax: (619) 400-5832

hartley@hartleyllp.com

lindner@hartleyllp.com

DUNCAN & ALLEN

Jon R. Stickman

Ashley M. Bond

Amy McDonnell

1730 Rhode Island Ave, NW, Ste. 700

Washington, DC 20036

Tel: (202) 289-8400

Fax: (202) 289-8450

jrs@duncanallen.com

amb@duncanallen.com

aem@duncanallen.com

Counsel for Plaintiff Turlock Irrigation District and the proposed Class